

Gynecare™

THERMACHOICE™ Uterine Balloon Therapy

Thermal Balloon Ablation Catheter and Syringe (Single-Use)

Read all directions, cautions and warnings prior to use.

This instructions for use provides directions for using the ThermoChoice Uterine Balloon Therapy (UBT) Catheter.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician with appropriate training.

Caution: This product contains natural rubber latex which may cause allergic reactions.

DEVICE DESCRIPTION

The ThermoChoice UBT System is a software controlled device designed to ablate uterine tissue by thermal energy. The system is comprised of a single-use balloon catheter, a reusable controller, umbilical cable, and power cord. The ThermoChoice catheter is designed for use only with the ThermoChoice controller.

The balloon catheter is 1) connected to the controller, 2) inserted through the cervix into the uterus, 3) filled with sterile, injectable fluid (5% dextrose in water) carefully stabilizing the pressure to 160-180 mmHg pressure, and 4) activated to thermally ablate endometrial tissue by maintaining a temperature of approximately 87°C (188°F) for 8 minutes.

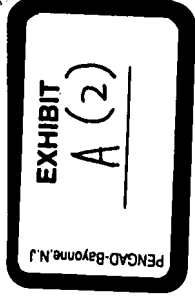
INDICATIONS

The ThermoChoice UBT system is a thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

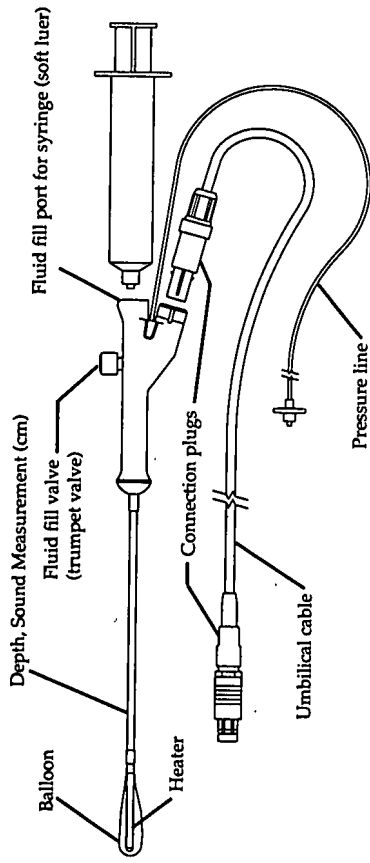
CONTRAINDICATIONS

The device is contraindicated for use in:

- A patient who is pregnant or who wants to become pregnant in the future.
- A patient with a history of latex allergy or who has demonstrated a sensitivity to latex material.
- A patient with known or suspected endometrial carcinoma (uterine cancer) or pre-malignant change of the endometrium such as unresolved adenomatous hyperplasia.
- A patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transverse myomectomy.
- A patient with active genital or urinary tract infection at the time of procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis).
- A patient with an intrauterine device (IUD) currently in place.



Single-Use Balloon Catheter (GC-EAC) and Umbilical Cable (GC-EAU)



WARNINGS

Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury.

- The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure.
- Endometrial ablation using the ThermoChoice UBT System is not a sterilization procedure. Pregnancies after ablation can be dangerous for both mother and fetus.
- Endometrial ablation procedures using the ThermoChoice UBT System should be performed only by medical professionals who have experience in performing procedures within the uterine cavity such as IUD insertion or dilation and curettage (D&C) and having adequate training and familiarity with the ThermoChoice system.
- Endometrial ablation procedures do not eliminate the potential for endometrial hyperplasia, or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- The UBT balloon catheter is for single use only — do not reuse, or resterilize.
- Do not treat patients for more than one therapy cycle in a given treatment session because of the potential for transmural injury to the uterus or injury to adjacent viscera.
- Use caution not to perforate the uterine wall when sounding the uterus or inserting the UBT balloon catheter. If a perforation is present, the procedure should be terminated immediately.

PRECAUTIONS

- The UBT balloon catheter, controller, and umbilical cable are designed as a system. To ensure proper function, never use other components with the UBT system.
- A starting pressure of 160 - 180 mmHg is recommended and typically requires 6-15 cc of fluid and may require as much as 30 cc. Titration to achieve a stable pressure (no fluctuations greater than ± 10 mmHg for at least 30 sec) prior to activating

the heating element is critical to proper functioning of the device. When inserting fluid, do not exceed a pressure of 200 mmHg. Typically, pressure levels decline slowly during the course of the procedure with the uterus relaxes. If a pressure of 160 - 180 mmHg cannot be reached with 30 cc or less of fluid, or if there is a rapid drop in pressure, remove balloon catheter and check for catheter leak and/or uterine perforation. Never add additional fluid during a therapy cycle. Rapid loss of pressure during a therapy cycle may indicate a uterine wall defect is present. Adding additional fluid to the balloon may create (or exacerbate if already present) a uterine wall defect such as a perforation.

- Those patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have a progestin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of the ThermoChoice UBT system has not been fully evaluated in patients:
 - with a large uterine cavity (>30 cc in volume or uterine sound >10 cm).
 - with a small uterine cavity (<2 cc in volume or uterine sound <6 cm).
 - with submucosal myomas, a bicornuate or septate uterus or a previous endometrial resection/ablation.
 - undergoing repeat endometrial ablation procedures.
 - who are post-menopausal.

ADVERSE EVENTS

In a study of 134 women, the most frequent events that have been reported following completion of the procedure include:

- Cramping/pelvic pain - Post-treatment cramping was reported in 91.8% of the patients which ranged from mild to severe as reported during the intra-operative period and immediate post-operative period. This cramping will typically last a few hours and rarely continues beyond the first day following ablation. The use of non-steroidal anti-inflammatory drugs (NSAIDs) prior to and following Uterine Balloon Therapy is usually sufficient to manage cramping and pelvic pain.
- Nausea and Vomiting - Nausea and vomiting were reported for 23.9% of the patients in the immediate hours following the procedure. This may be attributed to general anesthesia, and can be easily managed with medication.
- Endometritis was reported in 2.1% of patients. All patients responded to a course of oral antibiotics.
- Post-procedure symptoms such as pain, fever, nausea, vomiting, difficulty with defecation or micturition were reported. Failure of such symptoms to resolve over a reasonable period of time warrants evaluation by appropriate medical personnel.
- Hematometra was reported in 0.6% of patients treated in clinical studies conducted outside of the United States. In all patients, the hematometra was resolved with insertion of a uterine sound.
- A single perforation of the uterus was reported in a procedure conducted outside the United States.

OTHER POTENTIAL ADVERSE EFFECTS

The following adverse effects might be expected (potential), but have not yet been observed in clinical studies of the ThermaChoice UBT System:

1. Rupture of the Uterus
2. Thermal Injury to Adjacent Tissue
3. Heated Liquid Escaping Into the Vascular Spaces and/or Cervix, Vagina, Fallopian Tubes, and Abdominal Cavity.
4. Electrical Burn
5. Allergic Reaction to Latex
6. Hemorrhage
7. Infection
8. Pregnancy - Pregnancy following endometrial ablation is dangerous to both mother and fetus.
9. Post-ablation-tubal sterilization syndrome - This is a complication following endometrial ablation in women who have also previously undergone tubal ligation. The pathophysiology of this condition is believed to be related to the regeneration of endometrium in the cornual areas of the uterus. Blood from these glands can flow back into the proximal fallopian tubes in cases where the lower uterine segment is extensively scarred. The proximal oviduct becomes filled with blood and fluid causing symptoms similar to those of an ectopic pregnancy.

CLINICAL TRIAL

Conclusions: At twelve months of follow-up, balloon ablation was demonstrated to be at least as safe (with fewer intraoperative complications, less use of general anesthesia, and shorter procedure times), and as effective as hysteroscopic rollerball ablation in reducing menstrual bleeding to a clinically acceptable level in menorrhagic women who had completed their childbearing. Furthermore, statistically equivalent and significant reductions in patient-reported dysmenorrhea (mild, moderate, severe menstrual cramps), PMS symptoms (mild, moderate, severe common PMS symptoms), and overall impact of menses on lifestyle (scale of 1-10; 1 = none, 10 = severe) were experienced by both groups.

Purpose: The use of balloon thermal ablation for the treatment of menorrhagia for benign causes in an anatomically normal uterine cavity was compared with rollerball electrosurgical endometrial ablation with regard to safety and effectiveness. The primary effectiveness measure was a validated diary scoring system (adapted from Higham JM, O'Brien PMS, Shaw RW. Assessment of menstrual blood loss using a pictorial chart. Br J Obstet Gynaecol 1990;97:734-9). Success was defined as the reduction of excessive menstrual bleeding to normal flow or less. Secondary endpoints evaluated were overall percent decrease in diary scores and responses from a quality-of-life questionnaire. The endpoints for safety were based on the evaluation of adverse events associated with each procedure, including device-related complications, time of procedure, and type of anesthesia used.

Methods: This randomized, prospective, multicenter clinical investigation was conducted at 14 sites using investigators highly experienced with hysteroscopic rollerball endometrial ablation. All patients were ≥ 30 years old, premenopausal, and had completed childbearing. All had an anatomically normal uterine cavity ≥ 4 cm and ≤ 10 cm.

Three months of documented menorrhagia for benign causes was a requirement for inclusion and was confirmed with a diary score of at least 150 points. Endometrial biopsy and pap smear were required to rule out (pre)malignant uterine disease. No uterine thinning medications could be used for three months prior to treatment, and all patients underwent a three-minute suction curettage just prior to treatment. Selection of anesthesia regimen was left to the individual investigators. Treatment success was defined as reduction in menses to a diary score less than or equal to 75 in order to assure a return to eumenorrhea. In the original Higham study, a diary score of 100 had an 86% sensitivity and an 81% specificity for true menorrhagia for benign causes as determined by chemical analysis of the saturated pads.

Description of Patients: Two hundred seventy-five patients were randomized, 260 evaluated for safety, 255 of whom were eventually treated with either ThermaChoice Uterine Balloon Therapy (131) or rollerball ablation (124). A total of 125 UBT-treated patients and 114 rollerball-treated patients were available for Efficacy-Evaluation by having completed twelve-month follow-up. Baseline demographic and gynecological variables were statistically equivalent between the two groups with regard to age (UBT 40.2 years, RB 40.9 years), race, body mass index, mean baseline diary score (UBT 552.5, RB 570.5) and other criteria.

Results:

Table 1. Effectiveness at 12 Months

	ThermaChoice (n = 125)	Rollerball (n = 114)
Study Success Rate (Diary Score ≤ 75)	80.2%*	84.3%*
Decrease to Normal Bleeding Levels or Less (Diary Score ≤ 100)	84.8%*	89.5%*
Mean Percent Decrease in Diary Scores	85.5 + 22.5**	91.7 + 12.0**
% Patients with > 90% Reduction in Diary Scores	61.6%*	68.4%*
% Patients with Diary Scores = 0	15.2%**	27.2%*
Quality-of-Life		
% Patients with Anemia Pre/Post (HCT)	29.9% / 11.6%*	29.7% / 10.6%*
Satisfaction: Very Satisfied / Satisfied	85.6% / 10.4%*	86.7% / 12.4%*
% Patients with Reduction in Dysmenorrhea	70.4%*	75.4%*
Inability to Work Outside the Home (Pre/Post-Treatment Score)	39.7%* / 4.0%*	41.9%* / 2.7%*
% Patients Reporting Severe Impact on Life Pre/Post	70.3%* / 3.2%*	78.6%* / 1.8%*

*Not statistically different ($P > 0.05$). **Statistically significant ($P < 0.05$)

Table 2. Safety at 12 Months

	<u>THERMACHOICE</u> (n = 134)	<u>ROLLERBALL</u> (n = 126)
Intra-operative Adverse Events	None (0%)	2 fluid overloads 1 cervical laceration 1 uterine perforation (3.2%)
Post-operative Adverse Events	1 post-coital bleeding 3 endometritis 1 UTI (3.7%)	1 endometritis 1 hematometra 1 PATSS ¹ (2.4%)
Mean Procedure Time (minutes)	27.4**	39.6**
Cases Performed Under General Anesthesia	53.7%**	84.1%**

¹PATSS = post-ablation-tubal-sterilization syndrome *Not statistically different (P > 0.05).

**Statistically significant (P < 0.05)

PATIENT SELECTION

Menorrhagia can be caused by a variety of underlying problems including but not limited to, endometrial cancer, myomas, polyps, anovulation, drugs, and dysfunctional uterine bleeding. Patients should always be evaluated to determine the cause of their excessive uterine bleeding before any treatment option is initiated.

Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications, and hazards prior to the performance of any endometrial ablation procedures.

The patient selection criteria are:

- Documented diagnosis of menorrhagia for benign causes
- Completed childbearing
- Premenopausal
- Normal pap smear and endometrial biopsy
- Anatomically normal uterine cavity: standard sonography, saline infusion sonography, hysteroscopy, or hysterosalpingography within 6 months prior to performing UBT should be used to rule out submucous fibroids, large polyps, and congenital abnormalities.
- Uterine cavity depth of 6-10 cm
- Failed or contraindicated medical therapy.

PATIENT COUNSELING

As with any procedure the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation.

The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure. Patients of childbearing capacity should be counseled that endometrial ablation is not a sterilization procedure and should be provided an appropriate birth control method. Patients with childbearing capacity should be cautioned of the potential complications which may ensue if they should become pregnant.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge is described as bloody during the first few days; by approximately one week, serosanguinous; then profuse and watery thereafter.

PRETREATMENT PREPARATION OF PATIENT

The lining of the uterus should be thinned prior to UBT. This can be accomplished by timing the menstrual cycle to the early proliferative phase, administering pretreatment drugs such as danocrine or GnRH agonists, or performing suction or sharp curettage immediately prior to performing the endometrial ablation. The optimum pretreatment regimens have not been determined at this time.

It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued post-operatively as necessary to reduce intra-operative and post-operative uterine cramping.

DIRECTIONS FOR USE

Please read all directions, cautions and warnings prior to use.

1.0 SET-UP

1.1. The following items are required for use of the UBT System.

UBT System	Reorder #
1 sterile disposable UBT balloon catheter and syringe (30cc)	GC-EAC
1 umbilical cable	GC-EAU
1 controller	GC-EAS
1 power cord	GC-EAP

Medical Supplies

50cc sterile injectable 5% dextrose in water (D₅W)
sterile drape for umbilical cord
tenaculum, (weighted) speculum
uterine sound, cervical dilator(s)

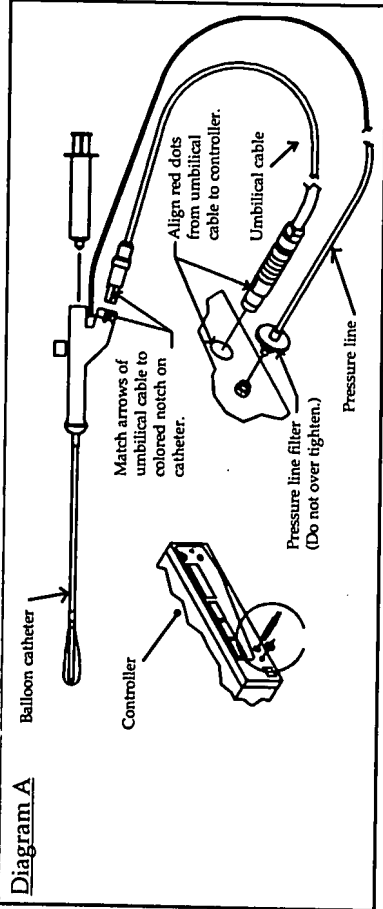
1.2 Open the sterile package containing the UBT balloon catheter and syringe. Disinfect umbilical cable as described at the end of this manual.

1.3 Make sure that the controller power is off before making the connection (Steps 1.4 - 1.6).

1.4 Plug the power cord into the back of the controller and into the wall outlet.

1.5 The umbilical cable includes a connector plug at each end to connect the balloon catheter to the controller. Visually inspect the cable and connector plugs to ensure there are no defects or signs of wear. Drape umbilical cable with sterile drape and attach the cable to the connector at the proximal end of the balloon catheter (match arrows of cable to colored notch on catheter). Attach the opposite end of the cable to the connection port on the front panel of controller. (Align red dots from umbilical cable to controller). (See Diagram A).

Note: When oriented correctly, the cable plugs will fit into the connectors easily and securely.



1.6 Connect the pressure line (pre-attached to balloon catheter) to the connection port (luer lock) on the front panel of controller. Tighten 1/4 turn only; do not over-tighten (See Diagram A). Periodically clean the entrance of the controller's port, using a cotton swab with 50% ethyl alcohol.

1.7 **TURN ON the controller POWER.** The Message Display will read:

Message Display:
 Note: N.NN = software revision level

REV. N.NN
 WARMING UP

After a few seconds, the Message Display will alternate between the following messages:

Message Display:

PRIME CATHETER

and

INSERT CATHETER
 FILL CATHETER

The pressure line **MUST** be connected to the controller **BEFORE** the balloon catheter is filled with fluid, or the device may not function properly.

2.0 CATHETER PRIMING

2.1 **FILL** the 30cc syringe with approximately 15-20cc of sterile injectable 5% dextrose in water (D₅W).

Use only sterile injectable 5% dextrose in water (D₅W). Use of other fluids may compromise system.

2.2 **CONNECT** syringe to the port in the proximal end of the balloon catheter. Do not overtighten syringe when connecting.

2.3 Point balloon catheter tip downward.

2.4 Press trumpet valve on top of balloon catheter handle and fill with 5-10cc of D₅W.

2.5 Press trumpet valve and evacuate fluid and air from balloon to a negative pressure of -150 to -200 mmHg (indicated by pressure display on controller).
 Note: You may need to purge air from syringe several times to attain desired negative pressure. You must release trumpet valve to maintain negative pressure. Air should be completely evacuated to optimize the function of the device.

2.6 The negative pressure creates a low-profile balloon insertion (balloon is drawn tight against catheter tip). Do not go beyond -300 mmHg. Check that negative pressure is maintained for at least 10 seconds before proceeding.

If negative pressure cannot be maintained for 10 seconds, remove balloon catheter and replace.

3. PRESSURE TITRATION

3.1 Fill syringe to 30cc with D₅W, purge air, and connect to balloon catheter (do not overtighten).

3.2 Using appropriate sterile technique and cervical/vaginal preparation, dilate cervix to 5mm if necessary.

3.3 Measure depth of uterus.

3.4 Wet outside of balloon with D₅W.

3.5 After sounding uterus, and wetting balloon, **SLOWLY INSERT BALLOON CATHETER** into uterus until tip is touching the fundus. Ensure depth indicated by markings on catheter is consistent with previous sound measurement. Use a tenaculum to hold cervix if necessary.

Ensure cervical dilation to 5mm and do not use excessive force during insertion, as such force can cause the balloon to tear or the catheter to perforate the uterine wall.

3.6 Press trumpet valve on top of balloon catheter and fill balloon slowly to pressure of 160-180 mmHg using 2-30cc of D₅W (Release trumpet valve to allow pressure to stabilize). Incrementally add small volumes to achieve a stable pressure (no fluctuations greater than ± 10 mmHg) of 160-180 mmHg for a minimum of 30 seconds. The pressure of the balloon against the uterine wall often precipitates uterine relaxation, thereby temporarily decreasing pressure.

For optimal results, it is extremely important to allow pressure to stabilize to 160-180 mmHg for 30-45 seconds before pressing **START** (◊) button. The pressure will ultimately stabilize with careful titration.

Note: Once the heater is activated, the pressure may initially rise 10-20 mmHg; the pressure may then drop slowly for the remainder of the procedure. The ending balloon pressure may be as low as approximately 100 mmHg, and is typically between 120-150 mmHg.

Note: Activation pressure for the procedure is ≥ 150 mmHg. The procedure cannot start until the pressure is over 150 mmHg.

Note: It is recommended that for very small uteri, pressure titration should occur towards the lower end of the range (i.e. 160 mmHg) to minimize any potential for overpressure readings during the heating process.


Do not over pressurize balloon during titration. The controller can not display pressure > 300 mmHg.

Optimal balloon volume depends on the potential volume of the uterine cavity and is typically 6-15cc at >160 mmHg (at start) and may be as great as 30cc. If pressure level cannot be reached with 30cc of fluid, remove balloon catheter and check for uterine perforation and/or balloon catheter leak. Replace balloon catheter if necessary.

4. TREATMENT

4.1 Message Display:

READY
PRESS START

When a steady pressure of 160-180 mmHg is maintained, press START () button on controller to activate heater.

Do not add fluid once heater is activated, as this could result in patient injury. Hold balloon catheter immobile during procedure (with valve oriented upwards).

4.2 After the start button is pressed, the controller activates the heater to achieve treatment temperature of 87°C (188°F) within 4 minutes. (This preheat cycle may take up to 4 minutes, but is usually 15-45 seconds.)

PREHEATING
TO 87°C

Note: If the treatment temperature of 87°C is not reached within 4 minutes, the controller will terminate the procedure. Remove fluid, remove catheter.

4.3 Message Display:

THERAPY CYCLE
87°C 8 MIN.

Once 87°C is reached, you will hear an audible alarm that indicates automatic activation of the 8-minute therapy cycle. Time elapsed is shown on the "TOTAL TIME" display (preheat + 8 minute therapy time).

Note: Pressure may rise slightly with initial heating. It is common to then see the pressure fall gradually during procedure.

4.4 When the treatment cycle is completed, the Message Display will alternate between the following messages:

CYCLE COMPLETE
REMOVE CATHETER

and

TURN POWER OFF

4.5 The controller automatically terminates the heater at the end of the treatment (cycle) and an audible alarm will sound. Total treatment time will be displayed on controller (preheat time plus 8 minute therapy time).

5. POST-TREATMENT

5.1 Wait approximately 30 seconds for fluid to cool and then remove fluid by drawing back on syringe while depressing trumpet valve. Remove all fluid from balloon. Remove balloon catheter. Check that entire fluid volume is with drawn.

5.2 Disconnect catheter pressure line from controller.

5.3 Disconnect umbilical cable from catheter by holding grey shell and pulling back.

5.4 Disconnect umbilical cable from controller by holding stainless steel ribbed shell and pulling back. Do not pull on the cable itself.

5.5 Discard catheter. Retain umbilical cable and disinfect for next case.

5.6 Power must be turned off before beginning another procedure.

ORDERING INFORMATION AND RELATED PARTS AND ACCESSORIES

Reorder Number	Description
GC-EAS	UBT System Controller
GC-EAC	UBT Balloon Catheter (sterile, single-use)
GC-EAU	UBT Umbilical Cable (reusable up to 20 applications)
GC-EAP	UBT Power cord (specify country)
GC-EAM	UBT System Manual
GC-EAI	UBT Instruction card